Remarks

The amendments

Claims 62, 82, and 83 have been cancelled.

Claims 60, 61, and 71 have been amended to recite the term "transgene" per the suggestion of the Patent Office. Office Action at page 2. Claims 86, 89 and 92 have been amended to remove the term "transgenic" in light of the amendment to claims 60, 61, and 71.

Claims 60, 61, and 71 have been amended to recite that the polynucleotide is operably linked to the promoter. Support for the operable linking of the polynucleotide encoding human PMS2 mismatch repair protein to a promoter can be found on page 16, lines 5-7: "The cDNA fragments were cloned into the BamHI site into the pSG5 vector, which contains an SV40 promoter followed by an SV40 polyadenylation signal."

Claims 60, 61, and 71 have also been amended to recite that cells of the transgenic mouse that express the transgene are hypermutable. Support for this amendment can be found at page 6, lines 14-19:

> The inventors have discovered a method of developing hypermutable cells and animals by taking advantage of the newly discovered alleles of human mismatch genes. Dominant negative alleles of such genes, when introduced into cells or transgenic animals, increases the rate of spontaneous mutations by reducing the effectiveness of DNA repair and thereby render the cells or animals hypermutable.

Claim 75 has been amended to recite that the phenotype 'conferred by' the gene of interest is analyzed. Support for this amendment can be found at page 10, lines 15-24 of the specification:

> Mutations can be detected by analyzing for alterations in the genotype of the cells or animals, for example, by examining

> the sequence of genomic DNA, cDNA, messenger RNA, or amino acids associated with the gene of interest. Mutations can also be detected by screening the phenotype of the gene. A mutant phenotype can be detected by identifying alterations in electrophoretic mobility, spectroscopic properties or other physical or structural characteristics of a protein encoded by a mutant gene.

Claim Objections

Claims 61-63, 71, 86, 89, and 92 stand objected to on the basis of the presence of the term "transgenic polynucleotide." The term "transgenic polynucleotide" has been replaced with the term "transgene" per the suggestion of the Patent Office. Office Action at page 2. The informalities have been corrected by the amendment. Applicant respectfully requests withdrawal of the objection.

Claims 60-62, 71-75 and 82, 83, 86, 87, 89, 90, 92, and 93 stand rejected under 35 U.S.C. 112, first paragraph

Claims 60-62, 71-75 and 82, 83, 86, 87, 89, 90, 92, and 93 stand rejected under 35 U.S.C. 112, first paragraph, for lack of enablement. The rejected claims are said to be not fully enabled by the specification for "the claimed mouse wherein the transgene is not operably linked to a promoter, is not expressed, or for expression and hypermutability in a fertilized egg per se." Office Action at page 3.

With respect to the "breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims." MPEP 2164.08.

Claims 60, 61, and 71 have been amended to recite that the transgene comprises a polynucleotide that is operably linked to a promoter and that cells of the transgenic mouse that express the transgene are hypermutable. As amended, claims 60, 61 and 71 are now commensurate in scope with the claims that the Patent Office has held enabled.

The remaining rejected claims—86, 87, 89, 90, 92, and 93—depend from either claim 61 or 71 and therefore incorporate the amendments made to those claims. Hence, all claims are enabled and Applicant respectfully requests withdrawal of the rejection.

Rejection of Claim 75 under 35 U.S.C. 112, second paragraph

Claim 75 stands rejected for indefiniteness. Specifically, the Patent Office stated that "it is not clear whether the claim is literally referring to a phenotype of the gene, itself, as in a characteristic of the nucleic (i.e. sequence), or if it is intended to refer to the phenotype of the mouse as an effect of a mutation in the gene of interest." Office Action at page 5.

A rejection under 35 U.S.C. 112, second paragraph, is appropriate only if the scope of the invention sought to be patented cannot be determined from the language of the claims with a reasonable degree of certainty. *See In re Wiggins*, 488 F.2d 538, 179 USPQ 421 (CCPA 1973).

Claim 75 has been amended to recite that the phenotype "conferred by" the gene of interest is analyzed. As amended, the meaning of claim 75 is now clear and Applicant respectfully requests withdrawal of the indefiniteness rejection.

A speedy allowance of all claims is requested in view of these amendments and remarks.

Respectfully submitted

Dated: 1 May, 2007

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